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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

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8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/598,604

Applicant(s)
Lamb

Examiner
Portner

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 15, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 5-34 is/are pending in the application.
- 4a) Of the above, claim(s) 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-21, and 31-34 is/are rejected.
- 7) ☒ Claim(s) 6-13, 31, and 32 is/are objected to.
- 8) ☒ Claims 1, 2, and 5-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

File

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DETAILED ACTION

Claims 3-4 have been canceled.

Claims 18-34 have been newly added.

Claims 1-2, 5-17 and new claims 18- 34 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

2. The abstract of the disclosure has been submitted.

3. The use of the trademarks at page 12, lines 3 and 7, Flagyl and Floxin, respectively, have capitalized.

4. Claims 1-2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the amendment of the claims.

5. Claim 4 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light the claim having been canceled.

6. Claims 5-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is partially obviated in so far as the claim has been amended to recite claim limitations

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that correlate with diagnosis but also has been maintained in part, in that the claims do not require one "SPR" to be distinguished from any other "SPR" (see response to arguments below).

7. Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, in light of the claim reciting a phrase that correlates with the preamble. See MPEP § 2172.01.

8. Claims 6, 10 and 12 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of claim 6, 10 and 12 to provide antecedent basis and definition of the sample and the secretion analyzed.

9. Claim 9 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of claim to clarify the testing step of claim 5 from which it depends.

10. Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Hartskeerl et al (1995), in light of the amendment of claim 1 to incorporate additional claim limitations.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ruffer et al (1997), in light of the amendment of claim 1 to incorporate additional claim limitations.

12. Claims 1-2 and 5 under 35 U.S.C. 102(e) as being anticipated by Relman et al (US Pat. 6,214,548), in light of the amendment and arguments set forth with respect to claim 1.

13. Claim 8 rejected under 35 U.S.C. 102(b) as being anticipated by Mennen (US Pat. 4,108,729), in light of the arguments set forth with respect to claim 8.

14. Claims 14-15 rejected under 35 U.S.C. 102(b) as being anticipated by Mennen (US Pat. 4,108,729), in light of the amendment of claim 14 to recite the phrase "a loop".

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Objections/Rejections Maintained

OK 15. The disclosure objected to because of the following informalities: at page 13, line 6 the phrase "(Rule 28(4)EPC)", no explanation of this phrase was provided.

16. Claims 5-13 rejected under 35 U.S.C. 112, second paragraph, for not distinctly claiming what is detected for reasons of record in paper number 4, paragraph 8.

17. Claims 5-8, 10-13 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, for reasons of record in paper number 4, paragraph 10.

18. Claim 17 under 35 U.S.C. 112, second paragraph, for reasons of record in paper number 4, page 5, last paragraph.

19. Claims 1-2, 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998) for reasons of record in paper number 4, paragraph 14 as applied to claims 1-4.

20. Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Monteiro-Leal et al (1996), for reasons of record in paper number 4, paragraph 15 as applied to claims 1-4.

21. Claims 5-6, 10, 12, 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998), for reasons of record in paper number 4, paragraph 17.

22. Claim 5 rejected under 35 U.S.C. 102(b) as being anticipated by Andrews et al (US Pat. 5,300,491), for reasons of record in paper number 4, paragraph 18.

23. Claims 5, 10-11 rejected under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat 5,827,200), for reasons of record in paper number 4, paragraph 19.

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24. Claims 5, 10, 11, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat.5,928,165), for reasons of record in paper number 4, paragraph 20 as applied to claims 5, 10-11.
25. Claims 5-7 rejected under 35 U.S.C. 102(b) as being anticipated by Mennen (US Pat. 4,108,729), for reasons of record in paper number 4, paragraph 21.
26. Claims 5, 12-13 rejected under 35 U.S.C. 102(b) as being anticipated by Yeh (US Pat. 5,725,373), for reasons of record in paper number 4, paragraph 22.
27. Claims 14-15, and 16 rejected under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat.5,928,165), for reasons of record in paper number 4, paragraph 24.
28. Claim 16 rejected under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat. 5,577,512; or 5,425,377), for reasons of record in paper number 4, paragraph 25.
29. Claim 17 rejected under 35 U.S.C. 102(b) as being anticipated by Birthistle et al (1996), for reasons of record in paper number 4, paragraph 26.
30. Claim 17 rejected under 35 U.S.C. 102(b) as being anticipated by Larson(US Pat. 6,180,136),for reasons of record in paper number 4, paragraph 27.
31. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Gray (US Pat. 54 74997), for reasons of record in paper number 4, paragraph 28.
32. Claims 5-8, 10-11, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353), for reasons of record in paper number 4, paragraph 30.

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33. Claim 9, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353) as applied to claims 5-8, 10-11, and 33 above, and further in view of Sheiness et al (US Pat. 5,776,694, for reasons of record in paper number 4, paragraph 31.

Response to Arguments

34. Applicant's arguments filed January 18, 2002 have been fully considered but they are not persuasive.

35. Applicant states the rejection of claims 5-13 under 35 U.S.C. 112, second paragraph has been obviated by amending the claim to correlate with the presence of infection.

36. It is the position of the examiner that while claim 5 has been amended to recite a "wherein" clause that clarifies what is tested, what the test detects is not distinctly claimed. The claim consistently recites the term "SPR" through out, but the specific characteristics of the "SPR" tested for, are not distinctly claimed. An "SPR" is functionally defined to be an single celled organism that rotates and has a surface that is "spiky". How one single cell organism that rotates and is spiky is distinguished from any other single cell organism that is spiky is not clearly pointed out. Claims 5-13 remain rejected under 35 U.S.C. 112, second paragraph, for not distinguishing one "SPR" from another, specifically what the "test detects is not distinctly claimed."

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*pending
5-7, 9-10, 12*

WJL 37. The rejection of claims 5-8, 10-13 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, because no specific tests or reagents or characteristics of "SPR" are recited in the claims to define that functional, biological or chemical indicators of the presence of "SPR" in the sample. See MPEP § 2172.01 is asserted to have been obviated by amendment of the claims (Amendment, page 12, paragraph 2).

38. It is the position of the examiner that no specific materials have been added to claim 5 that specifically define means for the diagnosis of an "SPR" infection. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

39. Applicant asserts the rejection of claim 17 under 35 U.S.C. 112, second paragraph has been obviated by amending the claim to depend from claim 1.

WJL 40. It is the position of the examiner that claim 17 has not been amended to depend from claim 1 as asserted in Applicant's amendment, and the specific "SPR" infection has not been defined to be any specific spiky rotating cells, wherein the definition provided for "SPR" includes both protozoa, bacteria. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

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41. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998) is asserted not to disclose all of the protozoan characteristics recited in amended claim 1.

42. It is the position of the examiner that Abou El Seoud disclose : biologically pure culture of a protozoan single celled organism, (*Trichomonas vaginalis*):

- i. known to have a spherical type shape of about 7-8 microns, (Ryu et al (1998, abstract)*T.vaginalis* of about 8 microns (see abstract line 6) depending upon the growth media;
- ii. flagellated (Introduction, page 263; a type of spiky membrane projection);
- iii. motile through rotating movements (page 263, introduction);
- iv. detected under microscopic inspection through reflection of light (page 265, paragraph 3, bottom of paragraph).
- v. formed colonies on Diamond medium (abstract);
- vi. will grow in an extracellular environment (epididymitis :page 263, Introduction section, grown on Diamond medium);
- vii. causes disease in humans.

By all comparable data, the biologically pure culture of Abou El Seoud anticipates the claimed culture. No specific species of protozoan is claimed and claim 2 is not limited to the ATCC deposit but includes stains that have the characteristics of the deposited strain “has the biological characteristics of ATCC Deposit”.

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43. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Monteiro-Leal et al (1996) is asserted to not have the characteristics now recited in claim 1.

44. It is the position of the examiner that Monteiro-Leal et al disclose a biologically pure culture of a single celled organism (see Figure 1, page 207):

i.spherical shaped (see Figure 2, page 208), and approx. 7-8 um (see bar=5.5um for Figure 2 and Figure 1, page 207)

ii. spiky membrane projections (ciliar-type beating, page 206, col. 1, third line from bottom; Figure 1, page 207, col. 1),

iii.refractile cell membrane (see Figure 3, refracted light shown)

iv. motile with rotating movements (abstract),

v.classified as a protozoan (page 206, col. 1), which will grow on Diamond medium (page 207, col. 1, materials and methods/cells section)

vi.living in an extracellular environment (cultured and interacts with epithelial cells, page 206, col 1); and

vii.causes disease in humans (see abstract of Benchimol et al (2001) that teaches T.foetus to be a human pathogen as well as cattle).

Inherently the culture of Monteiro-Leal et al anticipates the instantly claimed invention.

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45. The rejection of claims 5-6, 10, 12 under 35 U.S.C. 102(b) as being anticipated by Abou El Seoud (April 1998), is asserted to not describe a spherical protozoan of about 7-8 um in diameter that has spiky membrane projects, a refractile cell membrane and periodic colony formation.

46. It is the position of the examiner that Abou El Seoud disclose : biologically pure culture of a protozoan single celled organism, (*Trichomonas vaginalis*):

- i. known to have a spherical type shape of about 7-8 microns, (Ryu et al (1998)

T.vaginalis, of about 8 microns (see abstract line 6) depending upon the growth media;

- ii. flagellated (Introduction, page 263; a type of spiky membrane projection);

- iii. motile through rotating movements (page 263, introduction);

- iv. detected under microscopic inspection through reflection of light (page 265, paragraph 3, bottom of paragraph).

- v. formed colonies on Diamond medium (abstract);

- vi. will grow in an extracellular environment (warts, epididymitis, cystitis: page 263, Introduction section);

- vii. causes disease in humans.

By all comparable data, Abou El Seoud anticipates the claimed method of diagnosis, as Abou El Seoud diagnoses protozoan infection caused by an organism with the recited characteristics.

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47. The rejection of claim 5¹⁰ under 35 U.S.C. 102(b) as being anticipated by Andrews et al (US Pat. 5,300,491), is asserted to be directed to a method of treating and no mention of testing samples is described.

48. It is the position of the examiner that Andrews et al (US Pat. 5,300,491) disclose a method of diagnosing infection in a human patient that comprises:

obtaining a sample from a patient (col. 8, line 67; col. 13, lines 53; col. 18, lines 27-29) and

testing for the presence of a single celled organism that is spiky and rotating (motile protozoan) (samples were cultured, a type of testing: col. 8, line 68 and col. 9, line 33; col. 13, lines 53-55 (antibiotic sensitivity characterization); col. 18, lines 27-29). Andrews et al anticipates the now claimed method of diagnosing infection in a human patient that has "SPR".

49. The rejection of claims 5, 10-11 under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat 5,827,200), is asserted to not teach the methods step of obtaining a sample and testing the sample for the presence of SPR.

W/J 50. It is the position of the examiner Caillouette et al (US Pat 5,827,200) disclose a method of detecting a species of SPR infection in a female patient Claim 5 may detect any type of "SPR" with any type of characteristics, and Caillouette et al teach the diagnosis of infection caused by pathogenic bacteria, which would include bacteria that move by Brownian motion and have cilia

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or flagella, the method of Caillouette et al ('200) anticipates the claimed invention that is not so limited to diagnose any specific type of "SPR" infection.

The method of Caillouette et al comprising the steps of :

obtaining a sample from a patient using an instrument for the collection of a vaginal sample, wherein the instrument comprises a pH sensor that comes in contact with the sample (see abstract, Figure 7, claims 1, 10 and col. 3, lines 2-3); and

testing of the sample for a change in pH to aid in the diagnosis of infection (see col. 2, lines 7-9; col. 3, lines 37-49).

The reference anticipates the instantly claimed invention directed to an SPR organism.

51. The rejection of claims 5, 10, 11 under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat.5,928,165), is asserted to not teach the methods step of obtaining a sample and testing the sample for the presence of SPR.

52. It is the position of the examiner Caillouette et al (US Pat.5,928,165) disclose a method of detecting SPR infection in a female patient. As claim 5 may detect any type of "SPR" with any type of characteristics as long as the "SPR" rotates and is spiky, and Caillouette et al teach the diagnosis of infection caused pathogenic bacteria, which would include bacteria that move by Brownian motion and have cilia or flagella, the method of Caillouette et al ('165) anticipates the claimed invention that is not so limited to diagnose any specific type of "SPR" infection.

The method of Caillouette ('200) comprises the steps of :

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obtaining a sample of a patient, wherein the patient is a female and the sample is a vaginal or urethral secretion sample; and

testing the sample with an instrument that collects a vaginal or urethral sample (see col. 1, lines 24-25), wherein the instrument comprises a pH sensor that comes in contact with the sample (see abstract, Figures 1, 12, 13, 21, claims 1-26).

The reference anticipates the instantly claimed invention directed to an SPR organism.

53. The rejection of claims 5-7 under 35 U.S.C. 102(b) as being anticipated by Mennen (US Pat. 4,108,729), is asserted to not disclose a method of diagnosing "SPR", that the methods step of claim 6 requires the direct collection of the sample from a male urethra and claim 7 requires a pH indicator.

54. It is the position of the examiner that the sample of Mennen (US Pat. 4,108,729) is collected from the meatus of the male penis, defining a urethra sample, and the instantly claimed invention does not recite the *direct* collection of the sample from the male urethra. Claim 6 does not define how the sample is collected, but from where the sample is collected.

With respect to Applicant's assertion that the method of Mennen requires additional steps that differ from that of the instant invention, it is the position the claimed method recites open language which would permit additional methods steps, thus the method of Mennen is not excluded from anticipating the claimed invention.

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The method of Mennen is a method of diagnosing infection caused by a spiky (pili) rotating(movement) microorganism (Neisseria) in a patient, wherein the patient is a male and the method comprises:

obtaining a male urethral secretion containing a single celled organism (Neisseria), wherein collection of the sample is accomplished using an instrument that has a loop shape (surface used to collect sample, col. 2, lines 34-36) and comprises a pH sensor (color change section, see Figure 2); and

testing the secretion for its pH. The secretion is tested with a color change reagent indicative of pH, and is contained within and in direct communication with sample collection contact surface.. (See Figures 1-2 and 8, Figure 1, region 17 defining the handle type region).

The reference anticipates the instantly claimed invention.

55. The rejection of claims 5, 12-13 under 35 U.S.C. 102(b) as being anticipated by Yeh (US Pat. 5,725,373), is asserted to fail to disclose a means for diagnosing an SPR infection.

60/a 56. It is the position of the examiner that Yeh does disclose an instrument that could diagnose an SPR infection, wherein the instrument comprises a pH indicator positioned to contact the collected secretion, a collection step and a testing step in a method of diagnosing infection in a human patient, wherein the patient has gum disease and would evidence skin eruptions caused by the disease. The method comprising the steps of:

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collecting a secretion (acidity produced by bacteria, claim 1, sections (c) and (d)) using an instrument (the sample is collected on a litmus test paper: col. 2, lines 58-59), wherein the instrument comprises a pH sensor that comes in contact with the test sample; and

testing the sample secretion with a pH indicator contained within the instrument (col. 2, lines 5-10 and figures) .

Inherently the reference anticipates the claimed invention.

57. The rejection of claims 14-16 under 35 U.S.C. 102(e) as being anticipated by Caillouette et al (US Pat.5,928,165), is asserted to have been obviated by the recitation of the word “consists of a loop region”.

58. It is the position of the examiner that none of the claims recite the phrase “consists of a loop region”; all of the claims recite the phrase “comprises a loop”. Applicant’s arguments are not commensurate in scope with the instantly claimed invention.

Caillouette et al disclose and claim an instrument for the collection of a vaginal or urethral sample, wherein the instrument comprises a pH sensor that comes in contact with the sample (see abstract, Figures 1, 12,13,21, claims 1-26).

The recited intended use of the claimed instrument “for collecting secretions from the reproductive system of said male patient”, does not define over the applied prior art, in light of the prior art instrument comprising a loop collection means (see Figure 1, #13), a handle portion (see Figure 1, #10) and a pH sensor adjacent the collection means such that the pH sensing means

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comes in contact with the sample (see Figure 1, #12) and could be used to collect secretions from the reproductive system of said male patient. The instrument of Caillouette et al could be inserted into the distal end of the urethra of a male patient

59. The rejection of claim 16 under 35 U.S.C. 102(b) as being anticipated by Caillouette et al (US Pat. 5,577,512; or 5,425,377), is asserted to have been obviated by amending the claims to recite the phrase "consists of a loop region".

60. It is the position of the examiner that none of the claims recite the phrase "consists of a loop region"; all of the claims recite the phrase "comprises a loop". Applicant's arguments are not commensurate in scope with the instantly claimed invention.

(Apparatus) Caillouette et al (US Pat. 5,577,512; or 5,425,377) disclose and claim an instrument for the collection of a sample, wherein the instrument comprises:

a handle (see Figure 1, #10)

a collecting means comprising a loop; and

ws/a a pH sensor comes in contact with the sample (see '512: abstract, Figures 1, 10, 11, claims 1-38; see '377 figures and claims). The loop of Caillouette is not hollow, but is a loop shape which is adsorbent, and functions as a sample collecting means.

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61. The rejection of claim 17 under 35 U.S.C. 102(b) as being anticipated by Birthistle et al (1996); claim 17 rejected under 35 U.S.C. 102(b) as being anticipated by Larson(US Pat. 6,180,136); claim 17 rejected under 35 U.S.C. 102(b) as being anticipated by Gray (US Pat. 5,474,997) each are asserted to not “specifically teach the administration of metronidazole, itraconazole or ofloxacin for the treatment of an SPR infection.”

62. It is the position of the examiner that while the references do not recite the term “SPR”, the instantly claimed invention is directed to a genus of methods of “treating an SPR infection in a patient”, wherein the infecting agent is an organism that is spiky and rotates; the organism is not limited to any specific species of organism, but to any organism that can be treated with the recited medications and the infecting organism is **spiky and rotates**. “Spiky” is not an accepted genus for a pathogen and the term “rotates” does not define a specific species within the genus Spiky.

Birthistle et al disclose a method of treating a patient diagnosed with a protozoan infection, protozoans being a species of spiky rotating cell, the method comprises the steps of :

diagnosing infection (see col. 1, paragraphs 1-2) and

administering to the patient an SPR-inhibiting amount of metronidazole (col. 1, paragraph 3), wherein protozoan infection is inhibited, wherein a protozoan is a type of “SPR”.

Larson discloses a method of treating a patient diagnosed with a protozoan infection (see claim 33 and 41), protozoans being a type of spiky rotating cell, the method comprises:

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diagnosing infection (claim 41) and
administering to the patient an inhibiting amount of a fluoroquinolone, specifically ofloxacin (see claims 35 and 18), wherein infection is treated (claim 33), wherein a protozoan is a type of “SPR”.

Gray discloses a method of treating a patient diagnosed with a yeast or bacterial infection (see claim 1), bacteria and yeast having irregular cell surfaces, and evidence Brownian motion, the method comprising the steps of:

diagnosing infection (claim 1, a human in need of treatment due to infection); and
administering to the patient an inhibiting amount of a itraconazole (see all claims), wherein infection is treated. A bacteria or yeast that is spiky and rotates is a species of “SPR”.

63. The rejection of claims 7-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353) is asserted to not obviate the claimed invention because the instrument of Caillouette ‘165 would fail to properly collect the sample for examination because it possess a cotton swab as the collecting means and the claimed invention is a “loop region “sized and shaped for insertion into the distal end of the urethra for secretion collection”.

64. It is the position of the examiner that the claimed invention does not recite the phrase “loop region”, nor is the loop hollow, or required to be inserted for any extended length, but must only

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be insert able at the very end, the distal end of the urethra which would accommodate a cotton swab formulated to collect a male urethra secretion sample.

With respect to the assertion that a cotton swab would fail to “properly collect the sample”, it the position of the examiner that claims 5-8 (claims 5-6 rejected over Caillouette and claims 7-8 in view of Kalb et al) only require the collection of a sample that can be tested, the type of test is not limited to any specific type of test other than a pH test (claim 7). A liquid urethra secretion collected on a cotton swab would, and does define means for determining a proper pH evaluation of a sample. Caillouette et al evaluates pH from urethra samples properly from a cotton swab. If an additional test other than pH would not be properly collected and tested, the claims are not so limited to require any special type of sample nor any special type of testing, other than pH evaluation, which a swab can and does provide means to properly determine.

Applicant's arguments are not commensurate in scope with the instantly claimed invention.

65. The rejection of claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US Pat. 5,928,165) in view of Kalb et al (US Pat. 5,704,353) as applied to claims 5-8 above, and further in view of Sheiness et al (US Pat. 5,776,694) is asserted to not obviate the claimed invention because Caillouette '165 and Kalb fail to teach or suggest an instrument comprising a loop sized and shaped for insertion into the distal end of the urethra and Sheiness only discusses the use of microscopy for the identification of trichomonas.

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66. It is the position of the examiner that the instrument of Caillouette who teaches the formulation of an instrument that comprises a loop shaped component for obtaining a urethra sample from a patient could be used for the collection of a urethra sample from the distal end of a male patient and Kalb teaches that formulation of an instrument for obtaining both male and female urethra samples, wherein the instrument tests for various infection associated parameters, to include pH was known in the art at the time the invention was made.

Clearly the prior art teaches the formulation of an instrument for the testing urethra samples for at least pH, wherein the sample is obtained either from a male or female.

Sheiness et al was cited for teaching the classical testing of a sample for the presence of spiky rotating pathogens (see col. 3, lines 13-21), wherein the method of diagnosis comprised not only pH testing, said testing alone could result in false positive results, (see Sheiness, col. 2, lines 24-28) but also comprised visual evaluation through combining the sample with saline in order assess motility (rotating), size and physical structures (spiky) (see Sheiness, col. 3, lines 9, 18-19, 23).

The prior clearly teaches the evaluation of samples obtained from the urethra of a male or female patient, the utilization of an instrument that comprises a loop shape for the collection of the sample (Caillouette (collection end loop shaped/pH instrument; Kalb (collection/pH instrument for male or females, col. 7, lines 1-3; Sheiness collection end loop shaped/pH and motility testing) and combined sample testing that includes both pH testing (Caillouette, Kalb and

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Sheiness), coupled with the visual evaluation of the sample for the presence or absence of motile spiky rotating organisms (Sheiness, saline dilution of sample to assess motility).

No showing of unexpected results have been made of record, the prior art suggests, teaches and provides motivation (avoidance of false positive results) for the pH testing of urethra samples obtained from male and female patients coupled with motility testing of a saline mixed sample examined by microscopy; the applied reference obviate the instantly claimed invention.

Allowable Subject Matter

67. None of the claims are so limited to the deposited strain of pathogen given the ATCC number of PTA-2129, but are directed to strains that have the characteristics of this strain. If the claims were amended so to be limited to the Deposited strain, this would define over the prior art of record.

New Claim Limitations/New Grounds of Rejection

Information Disclosure Statement

68. The information disclosure statement filed February 4, 2001 has been considered prior to first action.

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Claim Objections

69. Claims 6,10, 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from preceding claims in the alternative; claims 6, 10 and 12 depend from claims 22-24 which are not preceding claims . See MPEP § 608.01(n).

70. Claims 6-9, 10-11, 12-13³¹⁻³² are objected to as being dependent upon withdrawn claims 22-24.

Election/Restriction

71. Newly submitted claims 22-31 and those portions of claims which depend from claims 22,23 and 24, specifically portions of claims 6-8,10,11,12,31,32^{11,13,32} directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The now claimed method of diagnosing nongonococcal urethritis is a species of invention not previously examined that is independent and distinct from a method of diagnosing SPR infection.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-31 and those portions of claims which depend from claims 22,23 and 24, specifically portions of claims 6-8,10,12,32, are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

72. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

73. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

74. Claims 1-21, 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All of the claims recite the claim limitation "forming periodic colonies of 2 to 10,000 cells" or in the case of claim 18 "colonies are 2 to 1000 cells". No original descriptive support for these limitations could be found.

Claims 1-2, 18-21 have been amended/submitted reciting the phrase "said organism is a protozoan", but the instant specification defines the organism to be "provisionally classified as a protozoan (page 7, line 20, instant specification)." The instant specification does not define the SPR as a protozoan, but is provisionally classified as a protozoan. The newly added phrase to claims 1-2 and 18-21, does not evidence original descriptive support in the instant specification.

Original descriptive support for the recitation of these claim limitations could not be found in the instant specification and are considered to be New Matter. Applicant is invited to point the specific location where original descriptive support for these claim limitations is found.

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75. Claims 1-2, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to recite the claim limitations of old claim 4. Claim 1 defines the diameter to be approximately 7-8 um, but which life cycle does the protozoan have this measurement? Protozoans cycle through more than one stage and can evidence different cell sizes depending on the stage in the cycle. The diameter could correspond to the colony morphology recited in the claim. Clarification of the recited diameter measurement relative to the recited protozoan and colonial morphology is requested.

Claim 2 depends from claim 1 and is directed to species of organism that have the characteristics of PTA-2129, which are now recited in claim 1. What other characteristic do the claimed strains have? How is claim 2 further limiting of claim 1?

Claim 5 has been amended to recite the phrase "the presence of SPR indicates an SPR infection". Claim 7 which depends from claim 5 defines an instrument that can test pH. Measuring pH alone does not define the presence of an SPR which is an organism that is spiky and rotates. How does pH indicate the presence of rotating motion and a spiky surface? The testing of the sample is not clear, in light of the claim having been amended and the type of testing not defined to be a test that detects the structural spiky characteristic and the functional rotating characteristic of the infection causing organism.

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Claim 18 is not further limiting of claim 1, which already recites that the colonies that are 2 to 10,000 cells, the range of which includes colonies of 2 to 1,000 cells.

Conclusion

76. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

77. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

May 28, 2002


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